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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,919	05/19/2006	Philippe Leferve	0600-1062	9816

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EXAMINER

SUTTON, DARRYL C

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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08/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/579,919	Applicant(s) LEFERVE ET AL.	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22 and 24-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 and 24-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/22/2010 has been entered. No new claims have been added.

Applicant's arguments filed 07/22/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-22, 24-27, 29, 30, 32-36 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lydzinski et al. (US 2003/0099692) in view of McCready et al. (Anal. Chem., 1950).

Lydzinski et al. teach oral films comprised of starch which are useful in delivering a variety of agents to produce pharmacological effects (Abstract and [0006]). Starch is intended to include all starches derived from natural sources [0008]. Typical sources of starches are legumes such as peas [0009]. The starch must be modified to achieve the desired film attributes [0010]. Chemically modified products include those which have been hydroxypropylated [0013]. Particularly suitable starches included hydroxypropylated starches [0017]. The starch component also comprises a cellulosic material or a gum, including hydroxyalkylcelluloses, microcrystalline cellulose, carrageenan, alginates or pullulan in amounts of less than 15% [0022], i.e. secondary film forming components. The starch is present in amounts ranging from about 50 to about 100% [0023]. At least one plasticizer may be added to increase the apparent flexibility of the films, including polyols, such as propylene glycol, sugar alcohols such as sorbitol or polyesters such as triethyl citrate in amounts from 0 to about 15% [0026]. The film may be made by a variety of processes known in the art; films may be formed by shaping into a solidified form by any technique known in the art, including wet casting, and extrusion molding; the solution may also be directly coated or sprayed onto another product such as a tablet and dried to form a film [0029]. A particular suitable process for preparing films is by making a solution of film components, applying the starch solution to a substrate, drying the coated substrate and removing the film from

Art Unit: 1612

the substrate [0030]. Conventional coating processes, i.e. processes known in the art, include coating in a fluidized bed and dip-coating.¹

Lydzinski et al. do not the legume starch with the specific amylose content of the instant claims.

McCready et al. teach that smooth peas such as First and Best peas and Alaska peas have an amylose content of 35% and 37% respectively (page 1157, 2nd column, Table III).

McCready et al. does not teach a film forming composition.

At the time of the invention, it would have been obvious to modify the composition of Lydzinski et al. to include the smooth pea starch of McCready et al. since Lydzinski et al. teaches the use of legumes such as peas. It would have been within the purview of the skilled artisan to use any source of peas and to evaluate its usefulness in the invention based on the broad disclosure of "sources of starches are legumes such as peas" of Lydzinski et al. It would have also been obvious to use a hydroxypropylated smooth pea starch since Lydzinski et al. teaches hydroxypropylated legume starches.

In regards to claims 29, 30, 32-34 and 41-43, the prior art does not specifically teach a pulverulent composition. However, the starch and the secondary film forming agent are in a dry form, i.e. powders or granules. It would be well within the purview of the skilled artisan to combine the two components to form a pulverulent composition to which the other components are added.

¹ Kim et al. US 6,123,963, column 6, lines 58-60.

Art Unit: 1612

In regards to claims 29, 30, 33 and 42, the prior art does not teach the specific weight percentages of the hydroxypropylated starch or of the secondary film-forming agent; or the weight percentage of the plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claims 29 and 30; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claims 29 and 30; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claims 33 and 42.

In regards to claims 32 and 41, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the

Art Unit: 1612

starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claims 32 and 41.

In regards to claim 35, since the composition of the prior art are comprised of substantially the same components as those of the instant claim, it would reasonably be expected to exhibit substantially the same viscosity as the instant invention.

Claims 31 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lydzinski et al. and McCready et al. as applied to claims 19-22, 24-27, 29, 30, 32-38 and 40-43 above, and further in view of Fuertes et al. (US 6,469,161).

Lydzinski et al. and McCready et al. are discussed above.

Lydzinski et al. and McCready et al. do not teach a hydroxypropylated and fluidification-treated pea starch.

Fuertes et al. teach a fluidification process for starchy materials (Abstract). Fluidification techniques can be combined with other types of modification, in particular with etherification reactions. Common properties obtained include increased film strength (column 2, lines 33-45). A fluidification stage can be preceded by other chemical modifications, such as hydroxypropylation reactions (column 3, lines 1-10, column 6, lines 53-67 and column 8, lines 39-55). Starchy materials of every origin and nature can undergo the fluidification process (column 5, lines 30-34). Starchy material is understood to be all modified starches resulting from chemical modification of native starches; particularly pea starch (column 7, lines 1-10). Chemical modifications include known techniques such as etherification, particularly hydroxyalkylation (column 7, lines

Art Unit: 1612

24-39). The process constitutes a new, particularly straightforward, inexpensive and high performance method of obtaining converted, notably fluidified/hydroxypropylated, starchy materials. The industrial sectors concerned with starchy materials complying with the instant invention include the food and pharmaceutical industries (column 10, lines 3-16).

Fuertes et al. do not teach a composition specifically comprised of pea starch and an amount of secondary film-forming agent; or the amounts of each; or a composition comprised of pea starch and an amount of secondary film-forming agent further comprised of 1 to 20% of microcrystalline cellulose; or further comprised of a from 5-15% of plasticizer.

At the time of the invention, it would have been obvious to modify the hydroxypropylated pea starch suggested by combining Lydzinski et al. and McCready et al. with the methods of Fuertes et al. to inexpensively produce a hydroxypropylated and fluidification-treated starchy material with increased film strength for use in the pharmaceutical industry, i.e., in preparing pharmaceutical compositions, as taught by Fuertes et al.

The prior art does not teach the specific weight percentages of the hydroxypropylated starch or of the secondary film-forming agent; or the amount of plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15

Art Unit: 1612

to 75% of instant claim 31; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claim 31; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claim 45.

In regards to claim 44, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claim 44.

Claims 19, 28, 37-39 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haasmaa et al. (US 2002/0032254) in view of McCready et al. (Anal. Chem., 1950), Leusner et al. (US 4,431,800) and Kim et al. (US 6,123,963

Haasmaa et al. teach hydrophobic dispersions used to suitable for the production of cast films as well as coating medicinal preparations (Abstract). The purpose of coating medicinal preparations is either to cover the disagreeable taste or smell of the drug, to protect the drug against external factors during storage or dosage, to facilitate the packaging, identification or to control the release of active substances [0019]. Polymers such as ethylcellulose are used in water-based coating preparations [0020]. The present invention is particularly suited for coating pharmaceutical preparations such as tablets, capsules and pellets [0022]. Hydrophobic starch dispersions can be produced containing a starch ether [0025]. The starch or a derivative thereof may be based on a native starch such as pea starch [0026]. The starch component is given plastic form by admixing it with a plasticizer in amounts of 0.01-95% by weight; any known plasticizer can be used, including triethyl citrate and castor oil [0031]. Typically the plasticizer is present in an amount which is 0.1 to 2 times the hydrophobic starch [0038].

Haasmaa et al. do not teach a specific embodiment comprised of a stabilized starch which has an amylose content between 30 and 45%; or the amounts of stabilized pea starch and plasticizer of claim 28; nor that the process of coating of claims 38 and 39.

McCready et al. is discussed *supra*.

Art Unit: 1612

McCready et al. does not teach a film forming composition.

Leusner et al. teach that hydroxypropylated starches are etherified starches that have reduced or decreased tendency toward retrogradation (column 1, lines 13-24), i.e. starches with improved stability.

Leusner et al. does not teach a composition comprised of stabilized pea starch.

Kim et al. teach that conventional processes for coating tablets, granules, pellets, crystals and capsules include coating in a fluidized bed and dip-coating (column 6, lines 58-65).

Kim et al. do not teach the film-forming composition of instant claim 19.

At the time of the invention, it would have been obvious to modify the composition of Haasmaa et al. to include the smooth pea starch of McCready et al. since Haasmaa et al. teaches the use of native starches such as pea starch. It would have been within the purview of the skilled artisan to use any source of peas and to evaluate its usefulness in the invention based on the broad disclosure of "native starches such as pea starch" of Haasmaa et al.

At the time of the invention, it would have been obvious to modify the smooth pea starch suggested by combining Haasmaa et al. and McCready et al. with the methods of Leusner et al. to produce a hydroxypropylated pea starch for use as the starch component since it is a stable starch ether. It would have been obvious to use the starch composition suggested by combining Haasmaa et al., McCready et al. and Leusner et al. in coating processes of Kim et al. since it teaches that conventional methods of coating capsules include fluidized bed and dip-coating.

Art Unit: 1612

In regard to claim 28, the prior art does not teach the specific amounts of stabilized pea starch and plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Kim et al. teaches amounts of plasticizer of 0.01 to 95% versus plasticizer in amounts of 1-2%; and that the amount of plasticizer will be from 0.1 to 2 times the amount of the starch component, i.e. the starch component can be from 0.1 to 47.5%, versus stabilized pea starch in amounts of 10 to 15% of the instant claim.

Applicants allege superior results, i.e. unexpected results, and cite Example 1, Table 3 of the instant specification as proof of the allegation.

The Examiner disagrees.

It is not possible to assess the allegation since the formulations of Table 3 are not compared to those of the closest prior art.

After analyzing, even assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate in scope with those showings. In Example 1, Applicants have only used 12.5% of hydroxypropylated pea starch with a degree of substitution of 0.2, and a hydroxypropylated-acid fluidification treated pea starch with a degree of substitution of 0.2, amylose content of 35-39% and a mixture of amylose rich and waxy corn starch with an amylose content of 42%, not any hydroxypropylated legume starch, not any legume starch or hydroxypropylated pea starch with any amylose content of between 30 and 45%, or any legume starch with an

Art Unit: 1612

any amylose content between 30-44% 35-40% or less than 45%, and not hydroxypropylated pea starch in any amount from 15-75% or 10-15%; has only used 1.25% of glycerol, not any plasticizer or any plasticizer selected from the group consisting of sorbitol, glycerol, polyethylene glycol, triethyl citrate, polysorbate, carnauba wax and hydrogenated castor oil or mixtures thereof, and not in any amount between 1-2% or 5-15%; has not used any secondary film-forming agent; has not used any adhesion promoter, i.e. microcrystalline cellulose; has only used fluidized bed spraying, not any coating method, immersion or casting; has only coated tablets, not any solid form, capsules or hard gelatin capsules; has not included any active substance; has only produced viscosities of 270 mPa·s for the hydroxypropylated pea starch with a degree of substitution of 0.2, 127 mPa·s for the hydroxypropylated-acid fluidification treated pea starch with a degree of substitution of 0.2, and 246 mPa·s for the mixture of amylose rich and waxy corn starch with an amylose content of 42%, not any viscosities less than 500 mPa·s. Accordingly, the claims are much broader than the showings of Example 1.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1612

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612